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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,548	04/19/2004	Dale B. Schenk	15270J-004747US	3885

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,548	SCHENK, DALE B.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *177 and 196-198* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *177 and 196-198* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *177 and 196-198* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 14 August 2006 have been entered. Claims 1 – 176 and 178 – 195 are canceled; claims 196 – 198 are new. Claims 177 and 196 – 198 are pending and under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. On p. 4 of the remarks, applicant indicates the specific sections of provisional application 60/080970 which provide support for the claimed invention. The instant application also claims benefit of provisional application 60/067740, filed 2 December 1997, however the examiner is unable to find support for administration of 10D5 antibody in that application. Priority is granted to 7 April 1998, the date the '070 provisional application was filed.

Information Disclosure Statement

4. Several items listed on the IDS filed 18 August 2006 were not received and thus have been crossed off the form. Those references have not been considered. There is no date for reference 639 and therefore the examiner cannot determine if it is prior art.

Withdrawn Rejections and Objections

5. The following rejections and objections made in the previous office action are withdrawn:

A. The objection to the specification is withdrawn in light of the amendments.

B. The objection to claim 177 is withdrawn in light of the amendments.

C. The rejections under 35 USC 112, first paragraph for lack of enablement and written description are withdrawn in light of the amendments and arguments.

D. The rejections under 35 USC 102 are withdrawn in light of the amendments, as neither reference teaches the invention now claimed. However, see the rejection, necessitated by amendment, under 35 USC 103.

E. All double-patenting rejections are withdrawn in light of the amendments as none of the cited patents or applications claim methods of treating disease by administering antibody 10D5. However, see the new double-patenting rejections, necessitated by amendment.

Rejections Necessitated by Amendment

Claim Objections

Claim 177 is objected to because of the following informalities: it recites the words "binds to" after "PTA-5129"; it appears this is a typographical error. Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 112

6. Claims 177 and 196 – 198 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' referral to the deposit of the hybridoma that produces antibody 10D5 on page 61of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that "the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be *irrevocably* removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository" is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required. Finally, there must be assurances that the deposit will be maintained for a term of at least 30 years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. See 37 C.F.R. § 1.806.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 197 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is confusing because it is not clear what is encompassed by "repeated when indicated". It is unclear whether this means that the antibody should be administered if levels are high, if they are low, or if a certain amount of time has passed since the previous administration.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 177, 196, and 198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker (EP 0613007, of record) in view of Hanan (1996. Amyloid:Int J. Exp. Clin. Invest. 3:130-133, reference 182 on IDS filed 4 August 2005).

Becker teaches administration of antibodies raised against beta-amyloid for treatment of Alzheimer's disease (see column 7 line 32 – column 8 line 30, for example), which is on point to claims 177 and 196. The methods include administration of pharmaceutical compositions comprising the antibodies (see column 2 lines 5 – 9 and column 8 lines 19 – 42). The amounts to be administered are therapeutically effective, as Becker clearly teaches that they are to be used as therapeutics (see column 7 lines 39 – 52). Becker's antibodies also include monoclonals, chimeric, humanized, and labeled antibodies (see column 5 line 51 – column 6 line 21 and column7 line 52 – column 8 line 5). Becker also teaches routes of administration as recited in claim 198 (see column 8 lines 19 – 42). However Becker does not teach antibody 10D5, as recited in claim 177.

Hanan teaches Alzheimer's disease is characterized by amyloid deposits formed by aggregation of A-beta, which is on point to claims 177 and 196 (see Hanan p. 130, first paragraph of Introduction). Hanan teaches that antibody 10D5 is particularly useful, as it inhibits formation of A-beta aggregates (see Figure 1 as well as p. 132, paragraph spanning the two columns). While Hanan does not teach that the antibody is identical to that deposited with

ATCC, the examiner notes that the deposit was not made until 2003 (specification, p. 61), and that Hanan teaches that antibody 10D5 was obtained from D. Schenk, who is the instant inventor (see p. 131 of Hanan). The antibody appears to be identical to that recited in the claims. The reference teaches that this antibody is the most effective in disrupting aggregates of all the antibodies tested (see Figure 1), and that it inhibits 80 – 90% of aggregate formation. Furthermore Hanan suggests that the results presented in the paper will be useful in developing antibody-based therapeutics for Alzheimer's (see p. 132, final paragraph). However Hanan does not teach methods of treating patients by administering antibodies.

It would have been obvious to one of ordinary skill in the art to use 10D5 antibodies as taught by Hanan in the method of Becker. The motivation would be to treat Alzheimer's disease, as taught by Becker. This motivation also comes directly from the prior art, as Hanan teaches that 10D5 antibodies are particularly effective in disrupting aggregates of A-beta, and also teaches that this is the mechanism underlying Alzheimer's disease.

9. Claims 177 and 196 – 198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Hanan as applied to claims 177, 196, and 198 above, and further in view of Miller (U.S. Patent 5,227,159 issued 13 July 1993).

The reasons why Becker and Hanan render obvious claims 177, 196, and 198 are set forth in the previous rejection. However neither reference teaches repeated administration of the antibody as indicated by measuring levels of antibody to A-beta in the patient.

Miller teaches administration of anti-HIV antibodies for treatment of disease. Miller also teaches measuring the levels of antibodies and repeating administration of the antibody as indicated by the circulating antibody levels (see column 15 lines 52 – 62), which is on point to claim 197. However Miller does not teach treatment of Alzheimer's disease by administration of 10D5 antibody.

It would have been obvious to monitor antibody levels and re-administer the antibody, as taught by Miller, when treating Alzheimer's disease as suggested by Becker and Hanan. The motivation to do so would be to optimize the circulating level of antibody, thereby ensuring that a therapeutic dose was maintained.

Double Patenting

10. Claims 177 and 196 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 133 – 136 of copending Application No. 10/232030 in view of Queen (US Patent 5,693,762). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant case are drawn to administration of 10D5 antibody, whereas in the '030 case they are drawn to administration of humanized antibodies. Queen teaches humanized antibodies and methods of making them that can be applied to any antibody (see column 2 line 35 - column 3 line 58 for a summary). Furthermore Queen teaches that humanized antibodies are advantageous when administered to people as they are less immunogenic than antibodies from other species (see abstract).

It would be obvious to humanize the antibodies, as doing so would minimize any adverse immune reaction.

This is a provisional obviousness-type double patenting rejection.

11. Claims 177 and 196 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18 – 20 of copending Application No. 10/704070 in view of Queen (US Patent 5,693,762).). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant case are drawn to administration of 10D5 antibody, whereas in the '030 case they are drawn to administration of humanized antibodies. Queen teaches humanized antibodies and methods of making them that can be applied to any antibody (see column 2 line 35 - column 3 line 58 for a summary). Furthermore Queen teaches that humanized antibodies are advantageous when administered to people as they are less immunogenic than antibodies from other species (see abstract).

It would be obvious to humanize the antibodies, as doing so would minimize any adverse immune reaction.

This is a provisional obviousness-type double patenting rejection.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel E. Kolker, Ph.D.
October 19, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER